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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,744	08/20/2003	Steve T. Lin	19870.052201	9151

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
04/20/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/645,744	LIN ET AL.	
	Examiner	Art Unit	
	BLESSING FUBARA	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112-183* is/are pending in the application.

4a) Of the above claim(s) *130-183* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112-129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges receipt of request for extension of time, response to restriction requirement and remarks filed 2/11/2011.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 112-121, in the reply filed on 02/11/2011 is acknowledged. The traversal is on the ground(s) that search of all claims do not present a burden on examiner since all the Groups encompass the same class and similar subclasses. This is not found persuasive because searching claims directed to composition having demineralized bone matrix without designation of the % amount is not the same as searching for demineralized bone matrix that is 20, 30 or 40% of the composition. Applicant did not say on the record that the art used for the broad designation that is open to any amount of the demineralized bone matrix could be used for the claims having demineralized bone matrix that is 20, 30 or 40% of the composition. However, since combination of two things generally involves mixing, which is the method recited in claim 122, the method of making the composition of claim 112 is examined with the composition. Therefore, upon further consideration claims 112-129 are examined and claims 130-183 are withdrawn from consideration.

The requirement is still deemed proper and is therefore made FINAL.

3. Election of demineralized bone matrix that is open: The claims as presented did not use the term open. However, the context of open stated in the election requirement refers to amount of the demineralized bone matrix that is open to any amount as opposed to claims that have demineralized bone matrix at 20, 30 or 40% of the composition.

4. The Amendment of 02/11/2011:

5. Applicant cancelled all the examined claims 1, 2, 4-11, 13, 16, 18, 19, 24, 27, 28, 30-37, 39, 43, 45, 46, 51 and 104-107 and filed new claims 112-183 in the amendment filed 01/25/2010. In response to the restriction requirement of 10/12/2010, applicant has canceled claims 12, 14, 15, 17, 20-23, 25, 26, 38, 40-42, 44, 47-50, 52-103 and 108-111 on 02/11/2011.

6. Claims 111-183 are thus pending.

Continued Examination Under 37 CFR 1.114

7. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/25/2010 has been entered.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 112-118 and 121-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarrett et al. (WO 98/12243) in view of Helm et al. ("Utilization of type I collagen gel, demineralized bone matrix, and bone morphogenetic protein-2 to enhance autologous bone lumber spinal fusion," in J Neurosurg 86: 93-100, 1997) or Bolander et al. ("The use of Demineralized Bone Matrix in the Repair of Segmental Defects," in the Journal of Bone and Joint Surgery, 1986, 1264-1274).

11. Jarrett teaches macromer carrier composition (abstract), the macromers are block copolymers including water soluble block, at least one biodegradable block and at least one polymerizable group (page 2, line 28 to page 3 line 1); at least one of the biodegradable block comprises carbonate or dioxanone and the macromer can also contain other degradable linkages or groups in addition to the carbonate or dioxanone (page 3, lines 1-4) with poly(hydroxyl acid) such as lactic acid and glycolic acid, polycaprolactones, polyorthoesters, polyanhydrides (page 3, lines 9-13; page 15, lines 4-23) as the other degradable linkages; such other linkage; the carbonate may come from trimethylene carbonate (Figures 1 and 3; page 15, lines 25-28); the structure of the macromer meets the structure of the claimed macromer in claims 1, 24, 27, 51, 104 and 106. The carrier composition is used as a drug delivery device for the delivery of therapeutic agents (page 1, lines 4 and 5; page 27, line 2 to page 28 line 13), used in sealing leaks in tissue (page 24, lines 9-29) and in orthopedic surgery, it can be used as bone repair (page 25, lines 11 and 12). The carrier composition may also contain free radical photoinitiator such as

eosin or eosin Y (page 26, lines 28-31) with the free radical initiator eosin or eosin Y meeting claims 114 and 115, 124 and 125. The carrier composition is aqueous (page 26, line 25) meeting claims 113 and 123. The carrier composition is applicable for human use (page 14, line 18; page 33, line 27). The presence of hyaluronic acid, dextran and heparin (page 14, lines 9-11) meets the limitation of additive in claims 117 and 118 and 127 and 128 and "to modify at least one of a physical and a chemical aspect of the composition" is a characteristic of the additive. See also page 9, line 22 to page 17, line 30. "Preselected shape" recited in claim 121 reads on any shape and as claim 121 is met. Jarrett also teaches that a combination of transition metal such as iron, peroxygen (peroxide) and stabilizing agent such as glucoronic acid generates free radicals to initiate polymerization (page 19, lines 1-4) meeting claims 116 and 126.

12. While Jarrett discloses the carrier composition of the claimed invention, and while Jarrett discloses that the carrier composition is a drug delivery device and specifically mentions the use of the composition for repair of bone, the carrier composition of Jarrett does not contain demineralized bone matrix material. However, it is known in the art that demineralized bone matrix is used for bone repair according to Helm (see the whole document) and Bolander (see the whole document). Therefore, taking the general teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that inclusion of demineralized bone matrix in the composition of Jarrett would effectively repair bone.

13. The combination of demineralized bone with the carrier composition of Jared involves mixing of the bone material into the gel carrier composition meeting claim 122 and the claims dependent thereon are rendered obvious as described above.

Response to Arguments

14. Applicant's arguments/remarks filed 01/25/2011 with respect to 1, 2, 4-11, 13, 16, 18, 19, 24, 27, 28, 30-37, 39, 43, 45, 46, 51 and 104-107 is moot in view of the cancelation of these claims.

15.

16. Claims 112-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarrett et al. (WO 98/12243) in view of Gertzman et al. (US 6,911,212).

17. Jarrett teaches macromer carrier composition (abstract), the macromers are block copolymers including water soluble block, at least one biodegradable block and at least one polymerizable group (page 2, line 28 to page 3 line 1); at least one of the biodegradable block comprises carbonate or dioxanone and the macromer can also contain other degradable linkages or groups in addition to the carbonate or dioxanone (page 3, lines 1-4) with poly(hydroxyl acid) such as lactic acid and glycolic acid, polycaprolactones, polyorthoesters, polyanhydrides (page 3, lines 9-13; page 15, lines 4-23) as the other degradable linkages; such other linkage; the carbonate may come from trimethylene carbonate (Figures 1 and 3; page 15, lines 25-28); the structure of the macromer meets the structure of the claimed macromer in claims 1, 24, 27, 51, 104 and 106. The carrier composition is used as a drug delivery device for the delivery of therapeutic agents (page 1, lines 4 and 5; page 27, line 2 to page 28 line 13), used in sealing leaks in tissue (page 24, lines 9-29) and in orthopedic surgery, it can be used as bone repair (page 25, lines 11 and 12). The carrier composition may also contain free radical photoinitiator such as eosin or eosin Y (page 26, lines 28-31) with the free radical initiator eosin or eosin Y meeting

claims 114 and 115, 124 and 125. The carrier composition is aqueous (page 26, line 25) meeting claims 113 and 123. The carrier composition is applicable for human use (page 14, line 18; page 33, line 27). The presence of hyaluronic acid, dextran and heparin (page 14, lines 9-11) meets the limitation of additive in claims 117 and 118 and 127 and 128 and "to modify at least one of a physical and a chemical aspect of the composition" is a characteristic of the additive. See also page 9, line 22 to page 17, line 30. "Preselected shape" recited in claim 121 reads on any shape and as claim 121 is met. Jarrett also teaches that a combination of transition metal such as iron, peroxygen (peroxide) and stabilizing agent such as glucoronic acid generates free radicals to initiate polymerization (page 19, lines 1-4) meeting claims 116 and 126.

18. While Jarrett discloses the carrier composition of the claimed invention, and while Jarrett discloses that the carrier composition is a drug delivery device and specifically mentions the use of the composition for repair of bone, the carrier composition of Jarrett does not contain demineralized bone matrix material.

19. But Gertzman discloses a composition for bone repair, the composition comprises a mixture of hydrogel, demineralized bone and cortical cancellous bone chips (see the whole document with emphasis on column 5, lines 26-65; column 6, lines 37-44; column 7, lines 24-31)

20. Therefore, taking the teachings of Jarrett and Gertzman, one having ordinary skill in the art at the time the invention was made would have been motivated to make a third composition comprising hydrogel, demineralized bone and cortical cancellous bone chips that would be effective for the same purpose of bone repair.

21. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the

very same purpose….[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

22. The combination of demineralized bone with the carrier composition of Jared involves mixing of the bone material into the gel carrier composition meeting claim 122 and the claims dependent thereon are rendered obvious as described above. Specifically, Gertzman discloses mixture of demineralized bone and hydrogel (column 5, lines 26, 29).

23. When cortical cancellous bone chips is mixed with the hydrogel, claims 119 and 129 are met.

24. No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613